(b) *Classification.* Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5300 Red cell indices device.

(a) *Identification.* A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.

(b) *Classification.* Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5350 Microsedimentation centrifuge.

(a) *Identification.* A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60598, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38789, July 25, 2001]

§ 864.5400 Coagulation instrument.

(a) *Identification.* A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies.

(b) *Classification.* Class II (performance standards).

[45 FR 60598, Sept. 12, 1980]

§ 864.5425 Multipurpose system for in vitro coagulation studies.

(a) *Identification.* A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

(b) *Classification.* Class II (performance standards).

[45 FR 60599, Sept. 12, 1980]

§ 864.5600 Automated hematocrit instrument.

(a) *Identification.* An automated hematocrit instrument is a fully automated or semi-automated device which may or may not be part of a larger system. This device measures the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

(b) *Classification.* Class II (performance standards).

[45 FR 60600, Sept. 12, 1980]

§ 864.5620 Automated hemoglobin system.

(a) *Identification.* An automated hemoglobin system is a fully automated or semi-automated device which may or may not be part of a larger system. The generic type of device consists of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

(b) *Classification.* Class II (performance standards).

[45 FR 60601, Sept. 12, 1980]

§ 864.5680 Automated heparin analyzer.

(a) *Identification.* An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient's circulation.

(b) *Classification.* Class II (special controls).

[45 FR 60601, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 58 FR 51571, Oct. 4, 1993]

§ 864.5700 Automated platelet aggregation system.

(a) *Identification.* An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.